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510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Ventana Medical Systems, Inc. developed the Ventana Anti-Desmin Primary Antibody for use on the Ventana ES automated immunohistochemistry system. Ventana Anti-Desmin Primary Antibody (clone DE-R-11) is substantially equivalent to other marketed immunohistochemical stians used in the identification of cells of normal and abnormal lineage as an aid in the diagnosis of anaplastic tumors.

Comparative Study

Supporting data for the equivalence statement is shown by the following study. Paraffin embedded preparations from normal and pathologic samples were tested using the Ventana Anti-Desmin Primary Antibody and compared to published results (Jones et al, 1990, Journal of Pathology, 162:29-33). Samples were obtained from excess tissues obtained for reasons other than the present study. Slides were processed on the Ventana ES Automated Slide Stainer, prepared for examination, and evaluated by a qualified pathologist for specific staining intensity and background staining.

Results

Specificity of the antibody was shown by appropriate staining of cells of myocytic origin and no staining of cells of non-muscle origin. Staining occurred in the muscle cells of normal skin, small intestine, stomach, prostate, tonsil, esophagus, testes, pancreas, cardiac muscle, and kidney tissues. In addition, the specificity seen in this study agrees with the data published by Jones et al, 1990.

The sensitivity of this antibody was shown by consistent staining of normal smooth and striated muscle and appropriate staining of myocytic sarcomas. As with any immunohistochemical reagent, the sensitivity is dependent on fixation, tissue processing, and slide preparation parameters. The negative control which was run with each tissue gave negative results. When compared with literature results, Ventana Anti-Desmin Primary Antibody consistently stained the same type of line cancers.

Inter-run reproducibility was determined based on samples of the same intesting tissue block on 11 different instrument runs. Staining was equivalent between all slides. Intra-run reproducibility was based on 10 samples of the same tissue within one run. The staining was

equivalent between the ten slides.